BASF

The Chemical Company

Helping Make Products Better™

Fed Express 7909 4662 5806

March 14, 2005

Document Processing Center
EPA East (Mail Code 7407M)
Attn: TSCA Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20460-0001

Subject: Notice in Accordance with TSCA Section 8 (e) –Results of a 2-week comparative toxicity study in Wistar Rats and C57 Black mice with 4-(1,1-dimethylethyl)-alpha-methyl-benzenepropanal (CAS No. 80-54-6) and 4-(1,1-dimethylethyl)-alpha-methyl-benzenepropanoic acid (CAS No. 66735-04-4)

Ladies and Gentlemen:

BASF Corporation is submitting results of a 2-week comparative toxicity study in Wistar Rats and C57 Black mice with 4-(1,1-dimethylethyl)-alpha-methyl-benzenepropanal (CAS No. 80-54-6) and 4-(1,1-dimethylethyl)-alpha-methyl-benzenepropanoic acid (CAS No. 66735-04-4) which was conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany

In this study 4-(1,1-dimethylethyl)-alpha-methyl-benzenepropanal and 4-(1,1-dimethylethyl)-alpha-methyl-benzenepropanoic acid were administered at a dosage of 50 mg/kg body weight/day to groups of 25 male Wistar rats and 25 male C57 Black mice each via oral gavage. For comparison, control groups of 25 male Wistar rats and 25 male C57 Black mice were treated with the vehicle (olive oil Ph EUR./DAB) at a volume of 5 ml/kg body weight/day.

BASF Corporation
100 Campus Drive
Florham Park, NJ 07932
Tel: (800) 526-1072
www.basf.com/usa

284517

BASF

The Chemical Company

Food consumption and body weight were determined weekly (from the first five animals per group). The animals were examined for clinical signs of toxicity or mortality at least once a day. After day 1, 2, 3, 4 and at the end of the administration period (day 15) 5 animals per group were deeply anaesthetized and the right testis and right epididymis were removed and sperm evaluation was carried out. Subsequently the animals were sacrificed by perfusion fixation. The left testis was examined light-microscopically and assessed.

For 4-(1,1-dimethylethyl)-alpha-methyl-benzenepropanal the results in rats are substantially similar with those, already submitted by Givaudan Corp. under section 8e to EPA (EPA/OTS; Doc # 89-910000322). In mice no significant toxicological effects were observed.

For 4-(1,1-dimethylethyl)-alpha-methyl-benzenepropanoic acid the following most relevant results occurred in rats:

There occurred no treatment-related effects on the general behavior, food consumption or body weight data development. At the end of the administration period (day 15) the number of homogenization resistant testicular spermatids and caudal epididymal sperm, the percentages of normal sperm and sperm motility data were distinctly affected if compared to the concurrent control group. The sperm of the substance-treated males did not show any motility and had an abnormality rate of nearly 100%. Such changes were not observed during the sperm analysis on treatment days 1, 2, 3 and 4. Regarding pathology, a diffuse tubular degeneration in the testes was observed in most males.

There were no significant toxicological effects in mice.

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy. BASF Corporation will update its MSDS with the new information.

Lastly, please note that our Corporate Headquarters are now located at Florham Park, NJ and not Mt. Olive, NJ. I request you to send all correspondence related to the TSCA 8 (e) submissions to the Wyandotte, MI address listed below:

Attn: Sree L. Jasti, Ph.D.
BASF Corporation
1609 Biddle Ave
Wyandotte, MI 48192-3799

BASF Corporation
100 Campus Drive
Florham Park, NJ 07932
Tel: (800) 526-1072
www.basf.com/usa

BASF

The Chemical Company

Please do not send any correspondence to either the new Florham Park, NJ address or the old Mt. Olive, NJ address. If you have any questions please call Dr. Sree Jasti at 734-324-5107. Thank you for your consideration.

Sincerely,

Sree Jasti

Sree L. Jasti, Ph.D.
Product Regulatory Center of Excellence
BASF Corporation
1609 Biddle Ave
Wyandotte, MI 48192-3899

Enc.

456th Mtg Letter.doc

BASF Corporation
100 Campus Drive
Florham Park, NJ 07932
Tel: (800) 526-1072
www.basf.com/usa